UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

KERRY NAGY, Personal Representative of the Estate of Sophia Nagy, Deceased

Plaintiff,

v.

LIVANOVA DEUTSCHLAND GMBH (f/k/a Sorin Group Deutschland GmbH) and LivaNova Holding USA, Inc. (f/k/a Sorin Group USA, Inc.),

Defendants.

Hon.

Case No.

COMPLAINT AND JURY DEMAND

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COMPLAINT

Plaintiff Kerry Nagy, Personal Representative of the Estate of Sophia Nagy, by way of Complaint against Defendants LivaNova Deutschland GMBH (f/k/a Sorin Group Deutschland GmbH) and LivaNova Holding USA, Inc. (f/k/a Sorin Group USA, Inc.) alleges as follows:

PARTIES, JURISDICTION, AND VENUE

1. Decedent Sophia Nagy ("Decedent") lived in Paw Paw, Michigan and was a citizen of Van Buren County in the State of Michigan.

2. Plaintiff Kerry Nagy ("Plaintiff") lives in Paw Paw, Michigan and is a citizen of Van Buren County in the State of Michigan. Plaintiff was appointed Personal Representative of the Decedent's estate by the Probate Court of the State of Michigan, Van Buren County.

3. Defendant LivaNova Deutschland GmbH (f/k/a Sorin Group Deutschland GmbH) is a foreign corporation organized under the laws of Germany with its principal place of business at Lindberghstrasses 25, D-80939, Munich, Germany.

4. Defendant LivaNova Holding USA, Inc. (f/k/a Sorin Group USA, Inc.) is incorporated under the laws of Delaware with its principal place of business at 14401 W 65th Way, Arvada, Colorado 80004.

5. The amount in controversy exceeds $75,000, exclusive of interest and costs.

6. By reason of the amount in controversy and diversity of citizenship, this Court has subject matter jurisdiction over this action. 28 U.S.C. § 1332.

7. Personal jurisdiction exists over Defendants, LivaNova GmbH and Sorin Group USA, Inc., in the United States and in Michigan due to the general and specific contacts they maintain. Defendants maintain those contracts presently and did so at all times material to this action.

8. Venue is proper in this District because a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction and because this Court has personal jurisdiction over Defendants. 28 U.S.C. § 1391.

General Factual Allegations

The University of Michigan Health System Announces Patient Exposure to Bacteria

9. On or about October 14, 2016, the University of Michigan Health System announced that nearly 7,000 of its patients were exposed to a mycobacterium chimaera ("M. chimaera"), a rare type of nontuberculous mycobacterium ("NTM")

10. The Health System's announcement came after the FDA announced a link between Sorin Sorin 3T Heater-Cooler System Heater-Cooler systems ("Sorin 3T Heater-Cooler system" or "Sorin 3T Heater-Cooler device") and NTM.

11. According to the Health System, patients who underwent surgery with cardiopulmonary bypass, including cardiac surgery, general thoracic surgery, or vascular surgery, between June 2011 and August 2016 were at risk for infection with NTM.

12. *M. Chimaera* occurs naturally in the environment and rarely causes illness. However, it poses a unique risk to patients whose organs or chest cavities are directly exposed to the bacteria during surgery.

13. Because *M. Chimaera* is a slow-growing bacterium, it can take years before manifestation of an infection, which most commonly causes endocarditis or a disseminated infection spread throughout the body.

14. Symptoms of *M. Chimaera* are non-specific and may include night sweats, muscle aches, weight loss, unexplained fever, and drainage or redness or the surgical wound.

15. While death is certainly a risk of this type of infection, there are treatments available. These include draining collections of pus or removing the infected tissue, coupled with rigorous administration of a series of appropriate antibiotics for prolonged periods of time. The type and period of treatment can vary greatly from patient to patient.

16. The diagnosis of an *M. Chimaera* infection requires targeted culturing and/or molecular diagnostic testing, the results of which take at least 6-8 weeks.

Defendants' 3T Heater-Cooler Systems as the Infection Source

17. Defendants designed, manufactured, marketed, and sold the Sorin 3T Heater-Cooler System.

18. The Sorin 3T Heater-Cooler System regulates blood temperature by circulating water through tubes into a heat exchanger, where blood is pumped into separate chambers during surgery. The water tanks and other areas where water pass through aerosolize a vapor containing NTM, which exits out of the device and is pushed into the ambient act of the operating room through the System's exhaust fan. Thus, when used in an operating room, the Sorin 3T Heater-Cooler System will produce contaminated vapor, which enters the sterile surgical field and the patient's open body.

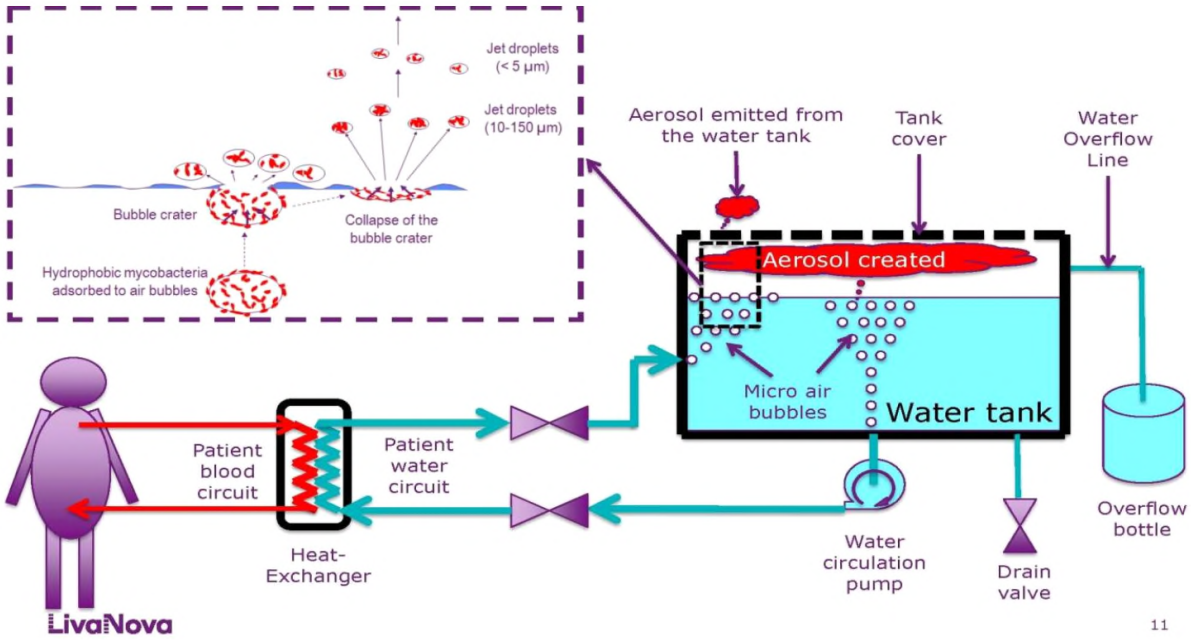

Figure 1 (From Defendants' publicly available presentation to the FDA Circulatory Devices Panel on June 2, 2016.)

19. Published studies dating back to the 1980s confirm that NTM is commonly found in water and has a high propensity to become airborne (aerosolize) through natural processes.[1]

[1] *See e.g.*, Wendt, *et al.*, Epidemiology of Infection by Nontuberculous Mycobacteria, III. Isolation of Potentially Pathogenic Mycobacteria from Aerosols, American Review of Respiratory Disease, 1980 ("Field experiments have confirmed the existence of a natural mechanism for the transfer of significant numbers of mycobacteria from water to air."); Falkinham, Mycobacterial Aerosols and Respiratory Disease, Emerging Infectious Diseases,

20. The medical and scientific community recognized the potential for contaminated water from heater-cooler devices to infect patients intraoperatively as early as November 2002.[2]

21. On or about September 19, 2005, Defendants Deutschland GmbH (then known as Sorin Group Deutschland GmbH) submitted a notice of intent to market the Sorin 3T Heater-Cooler system pursuant to the FDA's Section 510K premarket notification process because the device was substantially equivalent to a legally marketed device that is not subject to premarket approval. 21 CFR 807.92(a)(3)

22. On or about June 6, 2006, the FDA sent a letter to Sorin Group Deutschland GmbH, stating that it had determined that the Sorin 3T Heater-Cooler system was substantially equivalent to legally marketed predicate devices that do not require the more rigorous FDA Pre-Market Approval application process. 510K number K052601.

23. This FDA approval allowed the Defendants to market the Sorin 3T Heater-Cooler system subject to the conditions and regulation in the approval letter.

24. Any commercial distribution of the Sorin 3T Heater-Cooler System that does not comply with the conditions set forth in the letter are violations of the Federal Food, Drug, and Cosmetic Act.

25. Defendants were required to comply with all of the Federal Food, Drug, and Cosmetic Act's requirements, including, but not limited to, Registration and Listing (21 CFR part 807); Labeling (21 CFR part 801); Good Manufacturing Practice Requirements as set forth in the

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July 2003 ("Environmental opportunistic Mycobacteria are present in drinking water, resistant to disinfection, able to provoke inflammatory reactions, and readily aerosolized.").

[2] *See* The Heater-Cooler Unit—A Conceivable Source of Infection, Weitkemper, *et al*., The Journal of the American Society of Extra-Corporeal Technology, 2002.

Quality Systems Regulation (21 CFR part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act; 21 CFR 1000-1050)

26. Invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany, and the Netherlands since 2011. [3]

27. A public health investigation in Switzerland following six patient infections since 2011 included microbiological examinations of environmental samples that identified *M. Chimaera* contamination in heater-cooler units, including water samples from inside the units. Samples of the ambient air were positive for *M. chimaera* when the units were running, but negative when they were turned off.[4]

28. In April 2011, the FDA visited Defendant Sorin Group Deutschland GmbH's manufacturing facility in Munchen, Germany for a plant inspection and to discuss safety concerns with the Sorin 3T Heater-Cooler System. The FDA advised the company that these devices harbored dangerous bacteria and that it had failed to make a proper risk assessment for cleaning the devices to prevent bacterial infections in patients exposed in the operating room.

29. Defendants conceded to the FDA that this particular patient-risk was "not considered" because it was "not of concern."

30. During this inspection, the FDA also advised Defendants that the bacterial growth charts it used to justify the original instruction for device disinfection every 14 days allowed

[3] ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at http://ecdc.europa.eu/en/publications/Publications/mycobacterium-chimaera-infection-associated-with-heater-cooler-units-rapid-risk-assessment-30-April-2015.pdf (last accessed on June 26, 2018).

[4] Subsequent studies have further confirmed that the 3T aerosolizes *M. Chimaera* when powered on. *See e.g.*, Lyman, *et al*. Invasive Nontuberculous Mycobacterial Infections among Cardiothoracic Surgical Patients Exposed to Heater-Cooler Devices, Emerging Infectious Diseases, May 2017; Gotting, *et al*., Heater-Cooler Units: Contamination of Crucial Devices in Cardiothoracic Surgery, Journal of Hospital Infection, February 2016; Sommerstein, *et al*., Transmission of *Mycobacterium Chimaera* from Heater-Cooler Units during Cardiac Surgery Despite an Ultraclean Air Ventilation System, Emerging Infectious Diseases, June 2016.

bacterial overgrowth well in excess of safe standards in *just one and a half days*. The company admitted to the FDA that its cleaning instructions did not meet these standards and that it had no information to support the cleaning methods it disseminated to U.S. purchasers.

31. On or about January 28, 2014, Sorin Group Deutschland received a report from a health professional that one or more patients experienced an infection after surgeries in which the Sorin 3T Heater-Cooler Device was used. The hospital's investigation found bacteria in the tanks of all 3T devices at the facility.

32. On or about February 27, 2014, Sorin Group Deutschland filed a MAUDE Adverse Event Report with the FDA.

33. In May 2014, Defendants created a task force to investigate the risk of NTM infections from Sorin 3T Heater-Cooler Devices.

34. On or about June 19, 2014, Sorin Group USA received a report from a user facility's risk manager that fifteen patients tested positive for an "atypical mycobacterium infection." Out of the fifteen infected patients, four had died.

35. On or about June 20, 2014, the Greenville Health System, in Greenville, South Carolina, publicly announced that 14 patients had tested positive for a rare NTM. The majority of these patients were exposed to bacterium during open-heart surgeries. At that time the Greenville Health System indicated that there had been three deaths resulting from these infections. Within a month, the patient death toll increased to four.

36. Upon information and belief, this Greenville outbreak was the outbreak that was reported to Sorin Group USA on June 19, 2014.

37. On July 21, 2014, after the South Carolina Department of Health and Environmental Control investigated the Greenville outbreaks, it outline specific measures that

need to be immediately implemented related to "carioplegia machines" (i.e the Sorin 3T Heater Cooler Systems used by the Greenville Health System).

38. In July 2014, Defendants found NTM present in the water circuits of Sorin 3T Heater-Cooler Devices returned from the field. Thereafter, an "Important Information" letter was sent by Defendants to all Sorin 3T Heater-Cooler System users, informing them of the risk of NTM infections and reminding them of the importance of water disinfection procedures.

39. The July 2014 “Important Information” letter was sent “Attention: Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices.”

40. The July 2014 “Important Information” letter states as follows:

> *“We would like to bring to the attention of our customers a newly identified risk for cardiac surgery patients. Some cardiac surgery patients have been infected with a slow growing Mycobacterium chimaera....It is important to assure that your staff is aware of the Mycobacteria risk and to review your hygiene & surgical practices in the cardiac surgery theatre. This review should include your sampling and monitoring programs for your water sources, solution preparations and systems that use water in the cardiac surgery theatre. Among these water systems, heater cooler device(s) need strict adherence to the cleaning, disinfection and maintenance according to the operating manual....Without vigilant performance of the disinfection per the Operating Instructions, these organisms can multiply in a heater cooler device and potentially form biofilm....”*

41. The July 2014 "Important Information" letter continues:

> “*One of the highest risks of contamination for the patient is a direct contact transfer of water/solution droplets containing mycobacteria into the surgical field. Another risk that should be reviewed is the air distribution within the cardiac surgery theatre as this can be a transmission method for mycobacteria. The air conditioning as well as ventilation units including the heater cooler device fans need to be considered in that analysis.”*

42. The July 2014 "Important Information" letter also states:

> *“During the investigation work it has been identified that some hospitals heater cooler devices are contaminated. By way of caution and as a safety measure, Sorin reminds its customers using heater cooler devices about the importance of*

adhering to the correct maintenance of the device at all times and in particular to assure that the cleanliness of the water in the device is maintained. If the water is not properly disinfected and maintained, microbiological growth can occur within the device and over time biofilm may form."

43. The July 2014 "Important Information" letter states that "strict guidance to the instructions is mandatory for the safe use of the device."

44. The July 2014 "Important Information" letter also enclosed Defendants' latest version of the operating instructions for the Sorin 3T Heater-Cooler devices (hereinafter "2014 IFU")

45. According to Part 5.2 of the 2014 IFU, entitled, "Filling the water tanks," the "water tanks must be disinfected prior to operating the heater-cooler for the first time." Filtered tap water was to be used, and in order to prevent microbial growth, "100 ml of medical grade 3% hydrogen peroxide should be added to the filtered tap water." Every five days, 50 ml of hydrogen peroxide was to be added to the water tank, and the water "should be changed every two weeks."

46. According to Part 6.2.1 of the 2014 IFU, entitled, "Disinfection of the water circuits," "[t]he water circuits must be disinfected prior to operating the heater-cooler for the first time, when placing the unit in storage and if the hydrogen peroxide procedure was not routinely performed. In order to prevent microbial growth, we recommend performing the disinfection cycle every 3 months."

47. The disinfection procedure listed in Part 6.2.1 of the 2014 IFUs applies to the "water circuits," which includes the pump, heating and cooling tanks, fittings and all interconnecting tubing.

48. Part 6.2.1 of the 2014 IFU states, "[f]or disinfection of the water circuits, use Clorox® Regular-Bleach, Maranon or another SORIN GROUP approved disinfectant."

49. According to Part 6.2.1 of the 2014 IFU, either 6.76 fluid ounces of Clorox bleach or 420 milliliters of Maranon must be added to the Sorin 3T Heater-Cooler System's water tank to properly disinfect the device.

50. According to Part 6.2.2 of the 2014 IFU, entitled, "Protecting the water circuits from microbial growth," "[t]he water in the water circuits should be changed every two weeks and hydrogen peroxide added to prevent microbial growth."

51. On or about August 6, 2014, Sorin Group USA filed a MAUDE Adverse Event Report with the FDA relating to the Sorin 3T Heater-Cooler System. According to this Adverse Event Report, the investigation was ongoing but "[t]he common denominator for the cardiac surgeries is the profusion machine. The machine has been cultured and found to have the mycobacterium in the water."

52. Upon information and belief, in September 2014, Sorin Group Deutschland's own investigation revealed the presence of mycobacteria on units located at its manufacturing facility.

53. On or about January 13, 2015 Sorin Group Deutschland received a report from a health professional that "their 3T heater cooler machines in use appear to be contaminated with mycobacterium."

54. On or about February 13, 2015, Sorin Group Deutschland filed a MAUDE Adverse Event Report with the FDA.

55. On or about March 11, 2015, an article entitled "Prolonged Outbreach of Mycobacterium Chimaera Infection after Open-Chest Heart Surgery" (hereinafter "Sax article") was published in the journal, Clinical Infectious Diseases.

56. The Sax article reported findings of an investigation in which mycobacteria chimaera were cultured from water circuits of heater cooler-units and from air samples collected when the units were in use.

57. The Sax article concluded that "[t]he epidemiological and microbiological features of this prolonged outbreak provided evidence for the airborne transmission of *M.chimaera* from contaminated heater-cooler unit water tanks to patients during open-heart surgery."

58. On or about April 7, 2015, a laboratory contracted by the Defendants completed testing designed to evaluate the effectiveness of the Sorin 3T Heater-Cooler System's updated disinfection procedures in eliminating various bacteria, including mycobacteria chimaera

59. According to a White Pater authored by Sorin Group Deutschland, "[w]ith the enhanced hygiene concept, it is possible to achieve a bacterial count lower than 100 CFU/ml and no mycobacteria in the water of the Sorin 3T Heater-Cooler System heater-cooler."

60. Sorin Group Deutschland's White Paper specifically notes that its test results which demonstrated the efficacy of its "expanded hygiene concept," were limited to new devices only. The White Paper states as follows:

> ***Note**: all of the above results have been obtained on a new device released from production. This means that the initial level of bacterial contamination was limited, and specifically, that no biofilm or any other environment favorable to bacterial growth was present.* ***The efficacy of the same disinfectant on a highly contaminated device could not be demonstrated**. (emphasis added)*

61. Upon information and belief, by April 2015, the Defendants knew that their original disinfecting process was ineffective in eliminating mycobacteria chimaera from the Sorin 3T Heater-Cooler System, and that their "enhanced hygiene concept" was ineffective in eliminating mycobacteria chimaera from devices that were not new and/or already contaminated.

62. On or about April 30, 2015, the European Centre for Disease Prevention and Control issued a Rapid Risk Assessment, which linked cardiac surgery-associated mycobacterium chimaera infections to heater-cooler units.

63. According to the Defendants, in May 2015, they set up a "deep disinfection service" at Sorin Group Deutschland facilities, after realizing that "existing disinfection procedures would not be sufficient to reduce the risk of bacterial contamination of a heater-cooler device if it had not been properly maintained (according to IFU) for a long period of time, thus allowing a biofilm to grow in the water circuit."

64. On or about June 3, 2015, Sorin Group Deutschland authored a Field Safety Notice entitled, "Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler Devices."

65. The June 3, 2015 Field Safety Notice states as follows:

> "Sorin has become aware that the actual disinfection practices and water maintenance that some users have been performing are not always conducted according to our Instructions for Use. Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source of contamination."

66. The June 3, 2015 Field Safety Notice also provided customers with updated Instructions for Use regarding disinfection and maintenance procedures.

67. On or about June 11, 2015, the United Kingdom's Medicines and Healthcare Products Regulatory Agency issued a Medical Device Alert, warning of the risk of mycobacterium infection in patients undergoing cardiac surgery, associated with heater-coolers used with cardiopulmonary bypass machines.

68. On or about June 15, 2015, Sorin Group Deutschland authored a Field Safety Notice entitled, "Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler Devices."

69. The June 15, 2015, Field Safety Notice was sent "Attention: Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices."

70. The June 15, 2015 Field Safety Notice states as follows:

> *"Sorin has become aware that the actual disinfection practices and the water maintenance that some users have been performing are not always conducted according to our Instructions for Use. Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination."*

71. The June 15, 2015, Field Safety Notice also provided customers with updated Instructions for Use, dated February 2015, regarding disinfection and maintenance procedures.

72. In July 2015, the Bavarian Health and Food Safety Authority conducted an on-site investigation of Defendants' Munich, Germany manufacturing facility. Environmental samples were taken from the production line, on-site tap water, and from a used and disassembled heater-cooler device in the Defendants' service center. Six of twenty samples obtained were positive for mycobacteria chimaera.

73. On July 15, 2015, Defendants issued a Class II Recall of the Sorin 3T Heater-Cooler System's instructions for use ("IFU") because of "[p]otential colonization of organism, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

74. The recall directed customers to follow the new cleaning and disinfection procedures outlined the Field Safety Notice issued by the Defendants' Director of Quality Assurance on June 15, 2015.

75. According to this Field Safety Notice, the company's hygiene concept was "enhanced" by introducing the following modifications:

a. Use filtered tap water when filling the device

b. To make disinfection easier, switch from three different cleaning procedures (every five days, every two weeks and every three months), to just two (every seven days and every fourteen days)

c. The option to use peracetic acid instead of Clorox for disinfection

d. Use hydrogen peroxide in low dose for device preservation

e. Include all external turbing, bottles, and buckets in the disinfection process

f. Change to polyethylene tubing that meets national drinking water standards, and

g. Unused heater-coolers should be disinfected weekly

76. On or about August 6, 2015, Sorin Group Deutschland authored a letter, entitled, “Update to the Field Safety Notice for Heater-Cooler System 3T.”

77. According to the letter, “the Heater-Cooler System 3T Operating Instructions provided with the Field Safety Notice dated June 15, 2015, were intended for distribution to English speaking countries in the European Union (EU) rather than for the United States.”

78. Attached to the August 6, 2015, letter were the updated Instructions for Use for devices used in the United States.

79. Upon information and belief, Defendants knew or should have known that design and/or manufacturing defects in their Sorin 3T System made it susceptible to NTM colonization, *regardless of the cleaning and disinfection procedures used.*

80. On or about October 15, 2015, the FDA issued a Safety Communication warning hospitals and health care professionals of the association between heater-cooler devices and NTM infections.

81. In this Safety Communication, the FDA explained that it had received thirty-two Medical Device Reports of infections associated with heater-cooler device contamination.

82. On October 21, 2015, the U.S. Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance communication to raise awareness among health departments, healthcare facilities and providers of the association between NTM infections and the use of heater-cooler devices.

83. On or about December 11, 2015, the Pennsylvania Department of Health issued a Health Advisory on NTM infections among patients undergoing open-heart surgeries.

84. According to the Health Advisory, “epidemiological and microbiological findings from investigations in Europe and Pennsylvania convincingly support the conclusion that exposure to contaminated HCUs [heater-cooler units] is associated with NTM infection among patients undergoing open heart surgery on CPB [cardiopulmonary bypass].”

85. On December 29, 2015, the FDA issued a Warning Letter to Defendants, which stated that its inspection of Sorin's facilities in Germany and Colorado revealed that the Sorin 3T Heater-Cooler System devices had been "adulterated," meaning the "methods used in , or the facilities or controls used for, their manufacture, packing, storage, or installation [were] not in

conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR) Part 820."

86. In this Warning Letter, the FDA noted several other violations, including:

a. Failure to establish and maintain procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i)

b. Failure to validate a process, with a high degree of assurance and approved according to established procedures, a process where results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a)

c. The devices were misbranded in that Sorin failed or refused to furnish material or information respecting the device that is required by or under § 519 of the Act, 21 USC 360i and 21 CFR Part 803 – Medical Device Reporting.

d. Failure to adequately develop, implement, and maintain written MD procedures, as required by 21 CFR 803.17

e. Defendants' Sorin 3T System was misbranded due to its failure to notify the agency of its intent to introduce the device into commercial distribution as required by § 510(k) of the Act, 21 USC §360(k); and

f. Failure to notify the agency of significant labeling changes that affected the safety and effectiveness of the device (e.g. distributing the device with

modified instructions for use with respect to the operating, maintaingn, cleaning, and disinfecting of the device, among other modifications)

87. On March 17, 2016, a Class II recall of the Sorin 3T Heater-Cooler System was issued. This recall covers 1,125 devices.

88. The FDA "determined cause" for the recall is "device design."

89. In April 2016, a Euro Surveillance study following environmental investigations conducted between July 2014 and June 2015 determined that certain Sorin 3T Heater-Cooler Systems manufactured at Defendants' Munich, Germany production facility were contaminated with NTW on the production line or elsewhere at Defendants' manufacturing facility.

90. On June 1, 2016, an FDA Safety Communication following the Euro Surveillance findings noted that "this paper suggests a direct link between the M chimaera to which European patients were exposed and became infected during open-chest cardian curger, and one specific heater-cooler model – the Sorin 3T Heater-Cooler System." The FDA cautioned U.S. purchasers of the Sorin 3T Heater-Cooler System that if they purchased their unites before September 2014, they may have been shipped from Defendants' factory contaminated with *M. chimaera*.

91. In June 2016, a study published in the Journal of Emerging Infectious Diseases confirmed the airborne transmission of NTM via Sorin 3T Heater-Cooler Systems due to the ability of the System's exhaust fan to disrupt the ultra clean air ventilation systems of operating rooms. According to the study, aerosolization from the Sorin 3T Heater-Cooler System carried Mycobacterium chimaera particles a distance of up to 5 meters from the device.

92. On June 2-3 2016, the FDA hosed a Circulatory System Devices Panel for the Medical Devices Advisory Committee to address the public health risk posed by heater-cooler devices, and in particular, the Sorin 3T Heater-Cooler System.

93. During this Panel, the FDA noted that nearly 90% of the Medical Device Reports that it received between January 2010 and February 2016 citing device contamination and patient infection were attributed to the Sorin 3T Heater-Cooler System.

94. During this Panel, Defendants' representatives admitted that the Defendants were in the process of retrofitting Sorin 3T Heater-Cooler Systems with new design features, including, but not limited to, changing tubing materials from PVC to polyethylene to limit biolfilm contamination and introduction plugs in the water circuit to prevent sitting water.

95. On October 13, 2016, the CDC released the results of genome sequencing studies confirming that patients infected in Pennsylvania and Florida were directly linked to Defendants' Munich manufacturing site.

96. That same day, the FDA issued an updated Safety Communication instructing hospitals throughout the country to discontinue using Sorin 3T Heater-Cooler Systems manufactured before September 14, 2016 due to evidence of "point source contamination at the at the production site."

97. Studies published in 2017 concluded that the Sorin 3T Heater-Cooler Systems were most likely contaminated with M. Chimaera during manufacturing and that all M. Chimaera infections have been attributed to the Sorin 3T Heater-Cooler System.

Factual Allegations Specific to this Case

98. On September 5, 2014, Decedent underwent surgery at the University of Michigan Health System. During this surgery, Decedent's surgeon used Defendants' Sorin 3T Heater-Cooler System to provide cooling and re-warming of Decedent's blood.

99. On or about August 27, 2017, Decedent was diagnosed with sepsis and staphylococcus aureus bacteremia.

100. On September 8, 2017, Decedent passed away.

101. As a direct and proximate result of Defendants' negligence and liability-producing conduct as described herein, Decedent acquired a bacteria infection, which ultimately resulted in her death.

102. Neither Decedent nor Plaintiff was in any way responsible for Decedent's injuries.

COUNT I

Negligence- Design Defect

103. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

104. The Sorin 3T Heater-Cooler System is a product within the meaning of Michigan products liability law.

105. The Sorin 3T Heater-Cooler System was expected to reach, and did reach, users and/or consumers, including Decedent, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

106. Under Michigan products liability law, Defendants owed Decedent a duty to exercise reasonable care in designing and testing the Sorin 3T Heater-Cooler System.

107. Defendants designed the Sorin 3T Heater-Cooler System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

108. At all times material, the Sorin 3T Heater-Cooler System was used in a manner intended and/or foreseeable to the Defendants.

109. A patient or consumer using the Sorin 3T Heater-Cooler System would reasonably expect the device to be free fo significant defects.

110. The Sorin 3T Heater-Cooler System, as designed by the Defendants, colonizes bacteria.

111. The Sorin 3T Heater-Cooler System, as designed by the Defendants, directly transmits bacteria to patients during invasive surgery.

112. The foreseeable risks of using the Sorin 3T Heater-Cooler System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using Sorin 3T Heater-Cooler System.

113. Reasonable alternative designs existed for the Sorin 3T Heater-Cooler System. These alternative design would have eliminated or reduced the risk of bacterial colonization and/or transmission of such bacteria to patients undergoing invasive surgical procedures.

114. Reasonable and feasible alternative designs include, but are not limited to, measures to direct airflow away from the surgical field (i.e. a housing unit for the exhaust vent), reducing the force at which air is vented from the Sorin 3T Heater-Cooler System to a rate of less than 1000 cubic feet per minute, water reservoir isolation by using closed loop fluid management, an open water design to prevent inaccessible airspace, removable lids and parts for easy disinfection, disposable tank liners to prevent biofilm formation, and internal pasteurization or UV features to kill bacteria.

115. The failure to use feasible, reasonable alternative designs that eliminate bacterial colonization and the aerosolization of bacteria into the ambient air of operating rooms renders the Sorin 3T Heater-Cooler System unreasonably unsafe.

116. Defendants knew or should have known that NTM or other harmful bacteria were likely to colonize within the Sorin 3T Heater-Cooler System and be spread to patients during surgery through the system's exhaust vents.

117. Decedent's bacteria infection was caused by Defendants' conduct as follows:

a. Failing to conduct adequate safety and efficacy testing before placing the Sorin 3T Heater-Cooler System into the stream of commerce;

b. Failing to timely establish procedures for reviewing the design of the Sorin 3T Heater-Cooler System after receiving information that patients were developing bacterial infections as a result of surgeries using the Sorin 3T Heater-Cooler System;

c. Failing to timely establish procedures for validation or, where appropriate, review and approval of design change orders for the Sorin 3T Heater-Cooler System before their implementation as required under 21 CFR 820.30(i); and

d. Failing to design or redesign the Sorin 3T Heater-Cooler System to eliminate or mitigate bacterial colonization and/or transmission of such bacteria.

118. Decedent was proximately harmed by the design defects in the Sorin 3T Heater-Cooler System, as described above

WHEREFORE, Plaintiff, as Executor of Decedent's Estate and Decedent's Personal Representative, demands judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Michigan - together with interest thereon, costs, and attorneys' fees – in an amount greater than $75,000.

COUNT II

Negligence- Warnings Defects

119. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

120. The Sorin 3T Heater-Cooler System is a product within the meaning of Michigan products liability law.

121. The Sorin 3T Heater-Cooler System was expected to reach, and did reach, users and/or consumers, including Decedent, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

122. Defendants owed to Decedent a duty to exercise reasonable care in marketing, advertising, promoting, distributing and/or selling the Sorin 3T Heater-Cooler System.

123. Defendants marketed, advertised, and promoted the Sorin 3T Heater-Cooler System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

124. At all times material, the Sorin 3T Heater-Cooler System was used in a manner intended and/or foreseeable to the Defendants.

125. A reasonable patient or consumer of the Sorin 3T Heater-Cooler System would expect that the device be free of significant defects.

126. The Sorin 3T Heater-Cooler System colonizes bacteria, including *M. Chimaera*, and directly transmits such bacteria to patients during invasive surgery.

127. Defendants knew or should have known that NTM, or other harmful bacteria were likely to colonize within the Sorin 3T Heater-Cooler System and could be spread to patients during surgery through the exhaust vent.

128. The foreseeable risks of using the Sorin 3T Heater-Cooler System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the Sorin 3T Heater-Cooler System.

129. Decedent's infection was caused by Defendants' conduct as follows:

a) Failing to provide proper cleaning and disinfection procedures for the Sorin 3T Heater-Cooler System;

b) Failing to conduct proper validation studies to demonstrate the safety and efficacy of cleaning and disinfection procedures for the Sorin 3T Heater-Cooler System;

c) Failing to warn patients like Decedent and/or purchasers of the Sorin 3T Heater-Cooler System that the System colonized bacteria and unnecessarily transmitted it into the ambient air of operating rooms;

d) Failing to timely notify known purchasers of the Sorin 3T Heater-Cooler System that patients could be exposed to bacteria.

e) Failing to timely alert hospitals and patients to promptly test for bacterial infections when patients present with fever, pain, night sweats, joint and muscle pain, weight loss and fatigue after surgery using the Sorin 3T Heater-Cooler System

f) Failing to timely notify known purchasers of the Sorin 3T Heater-Cooler System to relocate the device to a location outside of the operating room during surgery to prevent patient transmission of NTM.

130. Decedent was proximately harmed by the warnings defects in the Sorin 3T Heater-Cooler System as described above.

WHEREFORE, Plaintiff, as Executor of Decedent's Estate and Decedent's Personal Representative, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of

the State of Michigan, - together with interest thereon, costs, and attorneys' fees – in an amount greater than $75,000.

COUNT III

Strict Liability – Manufacturing Defect

131. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

132. The Sorin 3T Heater-Cooler System is a product within the meaning of Michigan products liability law,

133. The Sorin 3T Heater-Cooler System was expected to reach, and did reach, users and/or consumers, including Decedent, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed.

134. Defendants manufactured the Sorin 3T Heater-Cooler System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

135. At all times material, the Sorin 3T Heater-Cooler System was used in a manner intended and/or foreseeable to the Defendants.

136. A reasonable patient or consumer of the Sorin 3T Heater-Cooler System would expect that the device be free of significant defects.

137. The Sorin 3T Heater-Cooler System, as manufactured by the Defendants, was contaminated with *M. Chimaera*.

138. The Sorin 3T Heater-Cooler System, as manufactured by the Defendants, directly transmitted *M. Chimaera* to Decedent, during her invasive heart surgery.

139. The foreseeable risks of using the Sorin 3T Heater-Cooler System, particularly severe bacterial infection and/or death, significantly outweigh the benefits conferred upon patients using the Sorin 3T Heater-Cooler System.

140. Decedent's infection and subsequent death was caused by Defendants' conduct as follows:

a. Failing to timely establish procedures or practices to prevent the Sorin 3T Heater-Cooler System from being contaminated with *M. Chimaera* on the production line or elsewhere at Defendants' production facilities

b. Manufacturing and selling the Sorin 3T Heater-Cooler System with *M. Chimaera* contamination that occurred on the production line or elsewhere at Defendants' production facilities; and

c. Failing to ensure proper workmanship, materials and labeling for the Sorin 3T Heater-Cooler System.

141. Decedent was proximately harmed by the manufacturing defects in the Sorin 3T Heater-Cooler System as described above.

WHEREFORE, Plaintiff, as Executor of Decedent's Estate and Decedent's Personal Representative, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Michigan - together with interest thereon, costs, and attorneys' fees – in an amount greater than $75,000.

COUNT IV

Strict Liability/Negligence – Failure to Warn

142. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herin.

143. At the time that Sorin 3T Heater-Cooler System left the possession ad control of the Defendants, it was in a defective condition and unreasonably dangerous because it contained warnings and instructions that were inadequate to alert consumers, include the University of Michigan Health System and Decedent, to the risks of the product's use.

144. Defendants failed to timely, properly, and adequately warn consumers, such as Decedent or her health care providers, as to the material risks of using the Sorin 3T Heater-Cooler System.

145. Defendants failed to timely, properly, and adequately warn consumers, such as Decedent or her healthcare provides as to a sufficiently save method of maintaining and disinfecting the Sorin 3T Heater-Cooler System.

146. Defendants knew or should have known about the risk of harm based on the scientific, technical, and medical information reasonably available at the time that the Sorin 3T Heater-Cooler System left the their control.

147. The Sorin 3T Heater-Cooler System's danger constituted a latent defect that gave rise to a post-sale duty to warn.

148. Had the Defendants provided adequate warning, Decedent would not have consented to the use of the Sorin 3T Heater-Cooler System during her surgery.

149. The Defendant's failure to adequately warn Decedent about the material risk of their product caused Decedent's death.

WHEREFORE, Plaintiff, as Executor of Decedent's Estate and Decedent's Personal Representative, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Michigan - together with interest thereon, costs, and attorneys' fees – in an amount greater than $75,000.

COUNT V

Negligence

150. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

151. Defendants owed a duty to consumers and the general public, who are the foreseeable end-users of the product, and specifically to Decedent, to use reasonable care in the manufacture, design, construction, formulation, testing, preparation, assembly, selling, advertising, packaging, labeling, and distribution of the Sorin 3T Heater-Cooler Device.

152. Defendants breached their duty of care and were negligent in one or more of the following ways:

a. Failing to ensure that the Sorin 3T Heater-Cooler System was safe;

b. Failing to design the Sorin 3T Heater-Cooler System so as to avoid an unreasonable risk of harm to persons undergoing procedures during which the device was used;

c. Failing to manufacture the Sorin 3T Heater-Cooler System so as to avoid an unreasonable risk of harm to persons undergoing procedures during which the device was used;

d. Failing to design and/or manufacture the Sorin 3T Heater-Cooler System without defects;

e. Failing to use reasonable care in designing and/or manufacturing the Sorin 3T Heater-Cooler System so as to avoid the likelihood that the device could harbor and/or grow bacteria, including mycobacteria chimaera;

f. Failing to use reasonable care in designing and/or manufacturing the Sorin 3T Heater-Cooler System so as to avoid contamination of the device;

g. Failing to use reasonable care in designing and/or manufacturing the Sorin 3T Heater-Cooler System so as to prevent the formation of biofilm within the device;

h. Failing to use reasonable care in designing and/or manufacturing the Sorin 3T Heater-Cooler System so as to avoid bacteria located within the device becoming aerosolized when the device is operated;

i. Failing to use reasonable care in designing and/or manufacturing the Sorin 3T Heater-Cooler System so as to avoid bacterial contamination of the device when cleaned and/or disinfected;

j. Failing to use reasonable care in developing and validating a safe and effective cleaning and disinfection protocol for the Sorin 3T Heater-Cooler System;

k. Failing to use reasonable care in the testing of the Sorin 3T Heater-Cooler System so as to avoid an unreasonable risk of harm to persons undergoing procedures during which the device was used;

l. Failing to use reasonable care in inspecting the Sorin 3T Heater-Cooler System so as to avoid an unreasonable risk of harm to persons undergoing procedures during which the device was used;

m. Failing to use reasonable care in instructing and/or warning health care providers and/or consumers of risks associated with the Sorin 3T Heater-Cooler System so as to avoid an unreasonable risk of harm to persons undergoing procedures during which the device was used;

n. Failing to use reasonable care in instructing and/or warning health care providers and/or consumers that the Sorin 3T Heater-Cooler System could harbor and/or grow bacteria, including mycobacteria chimaera;

o. Failing to use reasonable care in instructing and/or warning health care providers and/or consumers that bacteria can contaminate the Sorin 3T Heater-Cooler System and become aerosolized when the device is operated;

p. Failing to use reasonable care in instructing and/or warning health care providers and/or consumers that bacteria within the Sorin 3T Heater-Cooler System can become aerosolized, creating a condition in which bacteria may come in contact with a patient and contaminate the surgical site;

q. Failing to take reasonable measures to instruct and/or warn health care providers of proper cleaning and/or disinfection procedures for the Sorin 3T Heater-Cooler System;

r. Failing to take reasonable measures to instruct and/or warn health care providers and/or consumers that its IFU regarding cleaning and/or disinfection procedures for the Sorin 3T Heater-Cooler System are inadequate;

s. Failing to take reasonable measures to instruct and/or warn health care providers and/or consumers that its updated IFU regarding cleaning and/or disinfection procedures for the Sorin 3T Heater-Cooler System are inadequate;

t. Failing to timely, properly and/or adequately warn health care providers and/or consumers of the safety issues related to the Sorin 3T Heater-Cooler System;

u. Failing to timely, properly and/or adequately warn health care providers of proper cleaning and/or disinfection procedures for the Sorin 3T Heater-Cooler System;

153. Despite the fact that the Defendants knew or should have known that the Sorin 3T Heater-Cooler System posed a serious risk of harm to patients, they continued to manufacture and market the Sorin 3T Heater-Cooler System for use in health care facilities.

154. Defendants knew or should have known that patients, including Decedent, would suffer foreseeable injury as a result of their failure to exercise ordinary care, as described above.

155. Defendants' failure to exercise reasonable care in the design, manufacture, marketing, warning, distribution, and/or labeling of the Sorin 3T Heater-Cooler System was a direct, proximate, and producing cause of Decedent's death.

156. Defendants' negligence, set forth above, increased the risk of harm to Decedent and was a direct and proximate cause of her death.

157. As a direct and proximate result of Defendants' inaction and action, as set forth above, Plaintiff sustained severe and permanent injuries.

WHEREFORE, Plaintiff, as Executor of Decedent's Estate and Decedent's Personal Representative, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Michigan, - together with interest thereon, costs, and attorneys' fees – in an amount greater than $75,000.

COUNT VI

Negligence *per se*

158. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

159. The Stockert 3T is a medical device used during open-heart surgeries, which could expose patients to potential dangers. Defendants are presumed to understand the risks posed by its device.

160. Defendants had a duty to use reasonable care in the manufacture, design, construction, formulation, testing, preparation, assembly, selling, advertising, packaging, labeling, and warning of the Sorin 3T Heater-Cooler System.

161. As part of its duty to use reasonable care, Defendants was obligated to follow public laws and regulations enacted to protect the safety of persons such as Decedent, including 21 U.S.C. §§ 351(h), 352(o), and 352(t)(2).

162. The Sorin 3T Heater-Cooler Systems are misbranded pursuant to 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with good manufacturing practice requirements as stated in 21 C.F.R. Part 820.

163. Defendants violated 21 C.F.R. § 820.30(i) in that it failed to establish and maintain procedures for the identification, documentation, validation, verification, review, and approval of design changes before their implementation; procedures which, upon information and belief, would have identified problems associated with the device long before problems were first reported.

164. Specifically, Defendants did not ensure that its updated IFU related to cleaning and/or disinfecting the Sorin 3T Heater-Cooler System were adequate.

165. Defendants violated 21 C.F.R. § 820.75(a) in that it failed to adequately validate or verify a process with a high degree of assurance and according to established procedures, after it had implemented a new cleaning, drying, and disinfection process.

166. Additionally, Defendants did not perform adequate monitoring of manufactured devices after the new cleaning, drying, and disinfection process was implemented

167. The Sorin 3T Heater-Cooler Systems are misbranded pursuant to 21 U.S.C. § 352(t)(2), in that Defendants failed or refused to furnish material or information respecting the device that is required under 21 U.S.C. § 360(i) and 21 C.F.R. Part 803.

168. Specifically, Defendants failed to adequately develop, implement, and maintain written Medical Device Reporting (MDR) procedures; procedures which, upon information and belief, would have provided notice of deficiencies of the device at an earlier point in time.

169. The Sorin 3T Heater-Cooler Systems are misbranded pursuant to 21 U.S.C. § 352(o), in that Defendants did not notify the FDA of its intent to introduce the device into commercial distribution, as required under 21 U.S.C. § 360(k).

170. The Sorin 3T Heater-Cooler Systems are misbranded pursuant to 21 U.S.C. § 352(t)(2), in that Defendants failed or refused to furnish material or information respecting the device that is required under 21 U.S.C. § 360(i) and 21 C.F.R. Part 806

171. Specifically, Defendants failed to submit a written report to the FDA of any correction or removal of a device initiated to remedy a violation of the act caused by the device, which may present a risk to health.

172. Defendants did not submit a written report to the FDA of its updated IFU detailing the new cleaning and disinfection procedure.

173. Defendants had an obligation to not violate the law in manufacturing, designing, testing, inspecting, labeling, packaging, marketing, and selling the Sorin 3T Heater-Cooler System.

174. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of patients, such as Decedent, making Defendants liable to Plaintiff. Because Defendant violated the above referenced duties, it is *per se* negligent.

175. Defendants' negligence increased the risk of harm to Plaintiff and proximately caused Plaintiff's injuries and damages.

WHEREFORE, Plaintiff, as Executor of Decedent's Estate and Decedent's Personal Representative, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of

the State of Michigan, - together with interest thereon, costs, and attorneys' fees – in an amount greater than $75,000.

COUNT XII

Breach of Express Warranty

176. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

177. The Defendants warranted, both expressly and impliedly, through its marketing, advertising, distributors, and sales representatives, that the Sorin 3T Heater-Cooler System was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

178. During Decedent's surgery, the Sorin 3T Heater-Cooler System was being used for the original purposes for which it was approved and intended.

179. The Defendants are aware that health care providers and patients, including Decedent, would (and did) rely upon these representations made by the Defendants when choosing, purchasing, and using its products, including the Sorin 3T Heater-Cooler System.

180. Due to the defective and unreasonably dangerous design, labeling, manufacturing, and distribution of the Sorin 3T Heater-Cooler System – all of which was in violation of statutory and regulatory requirements, the product was neither merchantable, nor fit for the ordinary purposes for which it was sold.

181. The Sorin 3T Heater-Cooler System presented an unreasonable risk of injury to patients, including Decedent, during its foreseeable use.

182. The Defendants' negligence and statutory and regulatory violations, and the product's defective design, constituted a breach of the Defendant's express and implied

warranties, and such breaches were the direct and proximate cause of the incident and injuries to the Decedent.

WHEREFORE, Plaintiff, as Executor of Decedent's Estate and Decedent's Personal Representative, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Michigan, - together with interest thereon, costs, and attorneys' fees – in an amount greater than $75,000.

COUNT VIII

Breach of Implied Warranty

183. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

184. The Defendants warranted, both expressly and impliedly, through its marketing, advertising, distributors, and sales representatives, that the Sorin 3T Heater-Cooler System was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

185. During Decedent's surgery, the Sorin 3T Heater-Cooler System was being used for the original purposes for which it was approved and intended.

186. The Decedent, individually and/or by and through her healthcare provider, relied upon Defendants' implied warranties of merchantability in consenting to have her surgery performed with the assistance of the Sorin 3T Heater-Cooler System.

187. Defendants breached these implied warranties of merchantability because the Sorin 3T Heater-Cooler System was neither merchantable nor suited for the intended uses as warranted.

188. Defendants' breach of implied warranties resulted in the use of an unreasonably dangerous and defective product during Decedent's surgery.

189. As a direct and proximate result of the Defendants' breach of implied warranties and violations of statute and regulation, the Decedent contracted a fatal bacterial infection.

WHEREFORE, Plaintiff, as Executor of Decedent's Estate and Decedent's Personal Representative, demand judgment against Defendants, individually, jointly, vicariously, severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Michigan, - together with interest thereon, costs, and attorneys' fees – in an amount greater than $75,000.

COUNT IX

Wrongful Death – MCLA 600.2922

190. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

191. Plaintiff, Kerry Nagy, as Personal Representative of the Estate of Sophia Nagy, brings his action on behalf of the survivors/beneficiaries of the Decedent under the Michigan Wrongful Death Statute, M.C.L.A. 600.2922, and claims all damages available pursuant to the Act as a result of the death of Sophia Nagy.

192. Decedent Sophia Nagy died.

193. Decedent's death was caused by the wrongful act, neglect, or fault of Defendants.

194. Defendants' neglect, wrongful act, or fault was such that, if death had not ensued, Decedent would have been able to maintain an action to recover damages against Defendants.

WHEREFORE, Plaintiff, as Executor of Decedent's Estate and Decedent's Personal Representative, demand judgment against Defendants, individually, jointly, vicariously,

severally, and/or in the alternative, for such damages as may be permitted pursuant to the laws of the State of Michigan, - together with interest thereon, costs, and attorneys' fees – in an amount greater than $75,000.

PRAYER FOR RELIEF

Plaintiff, Kerry Nagy, requests that the Court enter judgment against the defendants as follows:

A. An award of compensatory and punitive damages, costs, and reasonable attorneys' fees, as permitted by law.

B. An aware of pre-judgment and post-judgment interest, as provided by law.

C. Leave to amend this Complaint to conform to the evidence produced at trial.

D. Such as relief as may be appropriate under the circumstances.

DEMAND FOR JURY

Plaintiff demands a trial by jury on all issues triable.

Respectfully submitted,

VARNUM LLP
Attorneys for Plaintiff

Dated: September 8, 2020

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